Ban on Amidopyrine and its derivatives

621. SHRI RAFIQUE ALAM: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Amidopyrine has been withdrawn for marketing in India but its dervia-tives are being promoted for human consumption;

(b) if so, names of its derivatives being allowed for marketing in the country;

(c) whether it is a fact that Mey-lers 1980, WHO Drug Information 1977, Manimili 1979, Martindale 1982 and American Medical Association Drug Evaluations 1973 have warned the dangerous and fatal effects of these derivatives;

(d) whether it is a fact that these derivatives are being marketed in India with tranquillisers;

(e) if so, the names of these formu-lations;

(f) whether it is also a fact that such combinations result severe low body temperature; and

(g) if so, what is the justification of allowing these derivatives and combinations for human consump-tion?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SA-ROJ KHAPARDE): (a) Yes, Sir.

(b) Analgin, a methanesulfonate derivative of Amidopyrine and some other derivatives of Amidopyrine are available in combination with other drugs.

(c) Agranulocytosis, a blood disorder is reported to be a rare adverse reac-tion in minimal sensitive population of a number of analgesic/anti-inflam-matory drugs including analgin.

(d) and (e) Statement annexed (*See* below)

(f) The drug is reported to be an excellent temperature lowering pain-killing and anti-inflammatory agent. As a result of its first property, if dose is exceeded, it may result in severe low body temperature.

(g) Bostons Epidemiological study, published recently have shown that the risk of agranulocytosis due to Analgin is very insignificant. As per the information available the benefit of the drug outweights its risks, so as to justify its continued marketing.

Statement

Combinations of-Analgin with Tranquillisers marketed in the Country

S.No.	Name of the Product	Composition	Marketed By
1.	Codolsic Tablets	Analgin Clidinium Bromide Diazepam	M/s. FDC, Bombay
2.	Famigin Tablets	Analgin Diazepam	M/s. Alkem,, Bombay
3.	Sedyn A Forte	Analgin Diazepam Diphenhydramine	M/s. M.M. Labs., Bombay.

Licences without Verification

622. SHRI RAFIQUE ALAM: Will he Minister of HEALTH AND FAMILY WELFARE be pleased to re-er to the answer to Starred Question 94 given in the Rajya Sabha on the 6th March, 1987 and state:

(a) whether it is a fact that fresh manufacturing licences as well as renewal of licences have been gran-ted without verifying quality control and testing laboratories as required under the Drugs and Cosmetic Rules by Drug Authorites;